

K092743

510(k) Summary of Safety and Effectiveness

JAN 15 2010

Proprietary Name: The Leibinger Advance Internal Midface Distraction System

Common Name: Bone Distraction System

Classification Name and Reference: Smooth or Threaded metallic bone fixation fastener
21 CFR §888.4760

Proposed Regulatory Class: Class II

Product Codes: JEY – Bone Plate

For Information contact:
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Date Prepared: September 4, 2009

Description:

The Leibinger Advance Internal Midface Distraction System is a distraction system consisting of the following major components: distractor frame, which incorporates connection screws for the plates, a removable activation rod, plates, and an activation key. The plates and frame initially stabilize and then gradually distract the osteotomy. The removable activation rod, covered with a protective sheath, is connected to the frame and provides the point of attachment for the activation key used to initiate the distraction of the osteotomy.

Intended Use:

The Leibinger Advance Internal Midface Distraction System is intended to be used in conditions of the cranium and mid-face for which osteotomy and segmental advancement are indicated.

Indications:

Treatment of cranial or midfacial conditions for which reconstructive osteotomy and segment advancement are indicated. The indications include conditions such as syndromic craniosynostosis (e. g. Apert, Crouzon, Pfeiffer, Antley Bixler) and midfacial retrusion. The device is intended to provide temporary stabilization and gradual lengthening of facial bones of the cranium and the midface. It is not intended to be used in the mandible.

Substantial Equivalence:

The Leibinger Advance Internal Midface Distraction System is substantially equivalent to other commercially available cranial and midface distraction systems. The following devices are examples of predicate systems: Cohen Distractor (K972154), Synthes Midface Distractor (K022005), Vazquez-Diner Intraoral Distractor (K964649) and Molina Orbital Malar Distractor (K003883).



Food and Drug Administration
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JAN 15 2010

Re: K092743

Trade/Device Name: The Leibinger Advance Internal Midface Distraction System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: December 29, 2009
Received: December 4, 2009

Dear Dr. Fitts:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

Anthony D. Watson
Anthony D. Watson, BS, MS, MBA
Director
Division of Anesthesiology, General Hospital,
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Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K092743

Device Name: The Leibinger Advance Internal Midface Distraction System

Indications for Use:

Treatment of cranial or midfacial conditions for which reconstructive osteotomy and segment advancement are indicated. The indications include conditions such as syndromic craniosynostosis (e. g. Apert, Crouzon, Pfeiffer, Antley Bixler) and midfacial retrusion. The device is intended to provide temporary stabilization and gradual lengthening of facial bones of the cranium and the midface. It is not intended to be used in the mandible.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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R.S.Betz DDS for Dr. K.P. Mulry (Acting)
(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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